UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,894	12/31/2003	Charles S. Neer	L-F/231/273	8901

7590 03/11/2010

WOOD, HERRON & EVANS, L.L.P.
2700 Carew Tower
441 Vine St.
Cincinnati, OH 45202

EXAMINER	
DOUKAS, MARIA E	
ART UNIT	**PAPER NUMBER**
3767	

MAIL DATE	DELIVERY MODE
03/11/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/749,894
Filing Date: December 31, 2003
Appellant(s): NEER, CHARLES S.

Charles Neer
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/30/2009 appealing from the Office action mailed 4/30/2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

The amendment after final rejection filed on 7/30/2009 has been entered by examiner at this time.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of claims 32 and 35-40 under 35 U.S.C. 101 has been withdrawn by the examiner as the Amendment After Final filed on 7/30/2009 has been entered by examiner which overcomes this rejection.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 21-40, in the reply filed on 2/2/2009 is acknowledged.

2. Claims 41-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/2/2009.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 32 and 35-40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

According to MPEP §2106 and (*In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008)), a method claim must meet a specialized, limited meaning to qualify as a patent-eligible process claim. The test for a method claim is whether the claimed method is (1) tied to a particular machine or apparatus, or (2) transforms a particular article to a different state or thing. In the case of claims 32 and 35-40, the claimed steps in the method are not tied to any machine or apparatus. Claim 32 recites providing a data collection routine, receiving input from the user, and updating a syringe definition, however, these steps are not tied to a specific machine or apparatus as required to be statutory subject matter. Further, claims 35-40 go to further defining the steps of claim 32 and do not add any machine or apparatus to tie the steps.

Independent claims 21 and 27 are not rejected under 101, because although they too are method claims for operating a motorized medical fluid injector system, both claims recite steps that are tied to the structure of the injector system, which therefore makes them statutory. The steps of entering a mode and storing a syringe definition are performed on the injector system, and therefore meet the requirements of Bilski cited above in that the method is tied to a particular apparatus.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 21-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canadian Patent No. 1,329,946 to Koenig (Koenig) in view of U.S. No. 6,200,289 to Hochman (Hochman).

<u>In Reference to Claims 21-24</u>

Koenig teaches a method of operation of an injector system comprising: entering a mode (instrument configuration mode) that permits use of service related functions by a service technician different from those involved in medical injection (p. 8, lines 11-17; p. 12, lines 8-10; p. 24, lines 8-27); changing the default settings of the injector (p. 26, lines 2-15); and storing these new settings in the injector (p. 26, lines 7-9, wherein the input settings replace, and therefore update, the default settings and are therefore stored in the system). Koenig further teaches wherein this injection pump can be a syringe pump (p. 4, lines 19-26). Koenig fails to explicitly teach receiving one or more syringe constants and then calculating an additional syringe constant based on the inputted constant. Hochman teaches an injector pump that comprises a memory 160 that stores data banks related to syringes (col. 8, lines 38-42). In storing the syringe

characteristics in the data bank of Hochman, a user would have entered the values for syringe length, stroke length, and volume and then stored it as a particular definition capable of being accessed during the operational mode (col. 9, lines 23-41). Further, if syringe stroke length and volume are known, then the user would be capable of calculating an additional syringe constant (e.g. cross-sectional area by dividing volume by the stroke of the syringe, col. 9, lines 50-53). This data bank stores information on different syringes in order to enable the user during the operational mode to select a syringe and receive its physical characteristics from the stored database without having to manually enter all of the syringe characteristics during operation setup (col. 9, lines 25-41).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Koenig to have the physical characteristics of a syringe (e.g. length, volume, stroke length) which can be stored in a memory data bank as taught by Hochman be the settings that the operator adjusts in the instrument configuration mode in order to enable the user during the operational mode to select a syringe and receive its physical characteristics from the stored database without having to manually enter all of the syringe characteristics during operation setup (col. 9, lines 25-41).

<u>In Reference to Claims 25 and 26</u>

Koenig in view of Hochman teaches the method of claim 21 (see rejection of claim 21 above). Koenig further teaches exiting the service mode and entering an

operational mode for use in medical procedures, wherein the operational routine relies on the syringe definition (p. 24, lines 8-18, wherein during the service mode the instrument is not in normal operation and infusing fluid, and therefore the service mode must be exited prior to pump operation).

In Reference to Claim 27-29

Koenig teaches a method of operation of an injector system comprising: entering a mode (instrument configuration mode) that permits use of service related functions by a service technician different from those involved in medical injection (p. 8, lines 11-17; p. 12, lines 8-10; p. 24, lines 8-27); changing the default settings of the injector (p. 26, lines 2-15); and storing these new settings in the injector (p. 26, lines 7-9, wherein the input settings replace, and therefore update, the default settings and are therefore stored in the system). Koenig further teaches wherein this injection pump can be a syringe pump (p. 4, lines 19-26). Koenig fails to explicitly teach receiving three syringe constants. Hochman teaches an injector pump that comprises a memory 160 that stores data banks related to syringes (col. 8, lines 38-42). In storing the syringe characteristics in the data bank of Hochman, a user would have entered the values for syringe length, stroke length, and volume and then stored it as a particular definition capable of being accessed during the operational mode (col. 9, lines 23-41). Further, if syringe stroke length and volume are known, then the user would be capable of calculating an additional syringe constant (e.g. cross-sectional area by dividing volume by the stroke of the syringe, col. 9, lines 50-53, and then calculating syringe diameter by

using the formula for the cross-sectional area of a cylinder. From these calculations, the user would then be capable of having syringe diameter be one constant that is input and stored in the system in addition to the volume and stroke length). This data bank stores information on different syringes in order to enable the user during the operational mode to select a syringe and receive its physical characteristics from the stored database without having to manually enter all of the syringe characteristics during operation setup (col. 9, lines 25-41).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Koenig to have the physical characteristics of a syringe (e.g. length, volume, stroke length, and diameter) which can be stored in a memory data bank as taught by Hochman be the settings that the operator adjusts in the instrument configuration mode in order to enable the user during the operational mode to select a syringe and receive its physical characteristics from the stored database without having to manually enter all of the syringe characteristics during operation setup (col. 9, lines 25-41).

<u>In Reference to Claims 30-31</u>

Koenig in view of Hochman teaches the method of claim 27 (see rejection of claim 27 above). Koenig further teaches exiting the service mode and entering an operational mode for use in medical procedures, wherein the operational routine relies on the syringe definition (p. 24, lines 8-18, wherein during the service mode the

instrument is not in normal operation and infusing fluid, and therefore the service mode must be exited prior to pump operation).

In Reference to Claims 32, 35, 36, 39, and 40

Koenig teaches a method of operation of an injector system comprising: providing a data collection routine that prompts a user to input information into the injector a mode to change the default settings of the injector, such as infusion rate (p. 26, lines 2-15); and storing these new settings in the injector (p. 26, lines 7-9, wherein the input settings replace and create a new setting, and therefore update, the default settings and are therefore stored in the system). Koenig further teaches wherein this injection pump can be a syringe pump (p. 4, lines 19-26). Koenig fails to explicitly teach receiving two syringe constants and calculating a third constant based on the input. Hochman teaches an injector pump that comprises a memory 160 that stores data banks related to syringes (col. 8, lines 38-42). In storing the syringe characteristics in the data bank of Hochman, a user would have entered the values for syringe length, stroke length, and volume and then stored it as a particular definition capable of being accessed during the operational mode (col. 9, lines 23-41). Further, if syringe stroke length and volume are known, then the user would be capable of calculating an additional syringe constant (e.g. cross-sectional area by dividing volume by the stroke of the syringe, col. 9, lines 50-53, and then calculating syringe diameter by using the formula for the cross-sectional area of a cylinder. From these calculations, the user would then be capable of having syringe diameter be one constant that is input and

stored in the system in addition to the volume and stroke length). This data bank stores information on different syringes in order to enable the user during the operational mode to select a syringe and receive its physical characteristics from the stored database without having to manually enter all of the syringe characteristics during operation setup (col. 9, lines 25-41).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of Koenig to have the physical characteristics of a syringe (e.g. length, volume, stroke length, and diameter) which can be stored in a memory data bank as taught by Hochman be the settings that the operator adjusts in the instrument configuration mode in order to enable the user during the operational mode to select a syringe and receive its physical characteristics from the stored database without having to manually enter all of the syringe characteristics during operation setup (col. 9, lines 25-41).

<u>In Reference to Claims 33 and 34</u>

Koenig in view of Hochman teaches the method of claim 32 (see rejection of claim 32 above). Koenig further teaches wherein one of the default settings is deleted during the process of inputting new settings and the new setting is stored in the memory of the system (p. 26, lines 7-9).

<u>In Reference to Claims 37 and 38</u>

Koenig in view of Hochman teaches the method of claim 32 (see rejection of claim 32 above). Koenig further teaches modifying one or more medical functions and parameters used in the injector that are affected by the updating (p. 15, line 10- p. 22, line 19, wherein the operational routine relies on the syringe definition as for example, during operation the minimum infusion rate that can be set is that set during service mode and stored in the system (p. 19, lines 17-18). Therefore, updating the syringe definition would result in changed settings for the injector system that would affect the calibration and use of the system).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,200,289	Hochman	3-2001

Canadian Patent No. 1,329,946 to Koenig (Koenig) entitled "User Interface for Medication Infusion System" (May, 1994).

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 21-40 were rejected under 35 U.S.C. 103(a) as being unpatentable over Canadian Patent No. 1,329,946 to Koenig (Koenig) in view of U.S. Patent No. 6,200,289 to Hochman (Hochman).

(10) Response to Argument

Applicant argues that nothing in Hochman suggests that the data regarding syringes stored in the data bank is provided by user entry and that Hochman does not describe a process for entry of the syringe parameters into the data bank. The reference to Koenig teaches an infusion pump that has a service mode (instrument configuration mode) that can be entered by the user to change default parameters of the system (p. 25, lines 18-25). Koenig further teaches wherein the system is capable of receiving user inputted data through a microprocessor (Figure 1) that is regarding the default parameters of the system (p. 26, line 7-p. 32, line 21) and then storing these inputted parameters within the system (p. 26, lines 7-9). Koenig is silent regarding one of the parameters that can be altered by user input being a syringe constant, which is where the reference to Hochman is used.

Hochman teaches an infusion pump system that has a microprocessor 152 with associated memory 160. The microprocessor is capable of receiving inputs from the user regarding the type of syringe being used (col. 8, lines 38-55; col. 9, lines 25-41) as well as allowing the user to access syringe physical characteristics that are stored within memory 160. This microprocessor taught by Hochman also calculates a syringe constant based on inputted syringe constants (col. 9, lines 46-53, wherein cross-sectional area is determined by using the volume and stroke or length parameters). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Koenig to have the microprocessor receive inputs

during the instrument configuration mode regarding syringe constants and also calculate another syringe constant (i.e. cross-sectional area) based on the inputted constants (i.e. stroke or length and volume) as taught by Hochman. As Koenig teaches the parameters that are input during this configuration mode are then stored in the system to replace the default parameters (p. 26, lines 7-9), the motivation to incorporating the input of syringe physical characteristics into the instrument configuration mode is that the user would not need to go through the steps of inputting the syringe characteristics during the separate operational mode of the system and instead have the desired syringe characteristics present in the system parameters. Therefore, the argument that Hochman does not teach entering syringe parameters in either an operational or service mode is not found persuasive, as the combination of the primary reference Koenig with Hochman teaches entering syringe constants in a "service" mode.

Applicant also argues that the memory data bank of syringe constants of Hochman may have been created at the factory and put into nonvolatile memory there and does not mention entering the data through a “service mode.” Although Hochman does not explicitly teach the user inputting syringe constants into the storage of memory 160, Hochman does teach that the storage contains physical characteristics about the syringe including length, volume, stroke length, and syringe force (col. 8, lines 38-55; col. 9, lines 25-41). It is inherent that at one point these particular physical characteristics of the syringe must have been input by a user in order for them to be within the memory's database. Therefore, although Hochman does not *explicitly*

describe the steps of inputting the syringe constants into the memory storage, inherently this step is met by the presence of syringe constants within the storage.

It is further noted by examiner that even if the memory data bank of syringe constants of Hochman was created at a factory and put into non-volatile memory as applicant argues, this would still read on the claims as presented. The step of 'entering a mode of the injector system that permits use of service-related functions…' is not limited by claim language to this step being performed in a clinical setting or outside the factory that the infusion system is produced. When the infusion system is produced in the factory and loaded with the memory, the "service mode" can be the mode utilized to initially program the memory of the system that stores the database of syringe information. Therefore, as syringe constants must inherently be programmed by the user during this programming step in order to produce the desired syringe database, the memory will "receive a syringe constant (i.e. volume, stroke length, length)" in this programming step; another constant can be calculated (i.e. cross-sectional area as described above) from the received constants (it is noted by examiner that the step of "calculating an additional syringe constant…" is not limited by claim language to be performed by the system, so if the user that is programming the system uses the constants of syringe volume and length and calculates the cross-sectional area from these values himself, the claimed step is met by this prior art; and the syringe constants are then stored as a data entry in the memory.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Maria Doukas

/MARIA E DOUKAS/

Examiner, Art Unit 3767

Conferees:

Kevin Sirmons

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

/Michael Phillips/

RQAS